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EXAMINER	
ARCHIE, NINA	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/682,130	**Applicant(s)** KLINMAN ET AL.
	Examiner Nina A. Archie	**Art Unit** 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 24 September 2009.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35,46,47,54 and 60-87 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35, 46-47, 54, 60-87 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to Applicant's amendment and response filed on 9/24/2009 has been entered into the record. Claims 1-34 are cancelled. Claim 35 is amended. Claims 61-87 are new. Claims 35, 46-47, 54, 60-87 are pending and under examination.

Objections/Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections/rejections are withdrawn.

a) Rejections to claims 1-5, 10, 12-13, 16, 18, 50, and 57-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of cancellation of claims.

b) Rejections to claims 1-5, 10, 12, 13, 16, 18, 43-45, 50, and 57-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in light of cancellation of claims.

c) Rejections to claims 12, 16, 35, and 50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light applicants amendment thereto and in light of cancellation of claims 12, 16, and 50.

New Grounds of Rejections

35 USC § 112

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 35, 54, 60-77, and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

In the instant case, the claims are drawn to a method of reducing the production of a cytokine or chemokine in a subject, comprising administering to the subject a suppressive oligodeoxynucleotide, wherein the oligodeoxynucleotide comprises from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof, thereby reducing the production of the cytokine or chemokine in the subject (claim 35); a method of reducing the production of a cytokine or chemokine in a cell *in vitro*, comprising contacting the cell with a suppressive oligodeoxynucleotide, wherein the suppressive oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof (claim 54);

The specification discloses SEQ ID NO: 1 as a suppressive oligodeoxynucloetide (ODN) which reduces the production of specific cytokines and chemokines induced by CpG. SEQ ID NO:1 meets the written description requirement. However, the rejected claims are directed to the recited methods administering a SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21. Consequently, the instant claim encompasses a vast genus of suppressive oligodeoxynucleotides and combinations of two or more said suppressive oligodeoxynucleotides aforementioned in the recited methods. Therefore to fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of suppressive oligodeoxynucleotides (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21)*,* applicant must adequately which specific ODNs, if any, have efficacy in thereby reducing the production of a given cytokine or chemokine in the subject and reducing the production of a cytokine or chemokine in a cell *in vitro*.

The specification discloses a suppressive ODN H154 (SEQ ID NO: 1), CpG ODN 1555 (SEQ ID NO: 27), and a neutral ODN 1612 in Examples (see Example 1 (see pp. 32-33). The specification discloses CpG DNA stimulates RAW 264.7 cells to produce a variety of cytokines and chemokines (TNFα, MIP-2, IL-6, and keratinocyte-derived cytokine [KC]) (see Example 2 (see pp. 34-35)). The specification discloses the suppressive ODN to CpG-stimulated RAW 246.7 cells significantly reducing production of the pro-inflammatory molecules (see Figure 2 and pg. 35 Example 2). The specification discloses when suppressive ODN were co-administered with the CpG DNA, the suppressive ODN blocks the CpG DNA-induced inflammation of the mouse lung by reducing the production (TNFα, MIP-2, IL-6, and KC), wherein, the CpG DNA triggered the production of pro-inflammatory cytokines and chemokines (TNFα and MIP-2) (see Example 3 (see pp. 35-36 and Figs. 3 and 4).

Moreover, the specification defines immunostimulatory CpG motifs as Imunostimulatory sequences that trigger macrophages, monocytes and lymphocytes to produce a variety of pro-inflammatory cytokines and chemokines (see pg. 12 lines 10-15). The specification also states that suppressive oligodeoxynucleotides and guaunosine-quadruplexes (G-tetrads) relates to the use of a class of DNA motifs that selectively inhibits or suppresses immune activation and are useful for inhibiting an immune response and for blocking immunostimulation caused by CpG motifs in vivo and in vitro (see pg. 19 lines 26-30 and pg. 20 lines 1-5). The specification discloses any oligonucleotide capable of forming G-tetrads may be used to suppress CpG DNA-induced immune activation (see pg. 21 lines 10-20).

Therefore the specification is limited to a method of reducing the production of TNFα, MIP-2, IL-6, and KC induced by CpG ODN in a subject comprising administering a suppressive oligodeoxynucleotide set forth as SEQ ID NO: 1. However, said data indicated does not provide a correlation between the structure of the claimed oligodeoxynucleotide and the functions set forth in the instant claims. Moreover, the limited number of suppressive oligodeoxynucleotide (i.e. SEQ ID NO: 1) aforementioned above disclosed is not deemed to be representative of the genus encompassed by the instant claims.

Applicant has not demonstrated that all cytokines and chemokines are reduced when administering to a subject, the genus of suppressive ODNs or a combination of two or more thereof aforementioned above. Although the specification defines immunostimulatory CpG motifs and discloses that suppressive oligodeoxynucleotides capable of forming G-tetrads may be used to suppress CpG DNA-induced immune activation, the specification does not provide guidance as to how to distinguish which ODNs are specifically suppressive or immunostimualtory CpG stimulated which indicate producing or reducing cytokines or chemokines as claimed in the recited method. Applicants have not demonstrated that any examples aforementioned above are representative of the genus of oligonucleotides excluding SEQ ID NO: 1 or a combination including SEQ ID NO: 1 for the recited methods as claimed. Moreover, Applicant has not demonstrated that suppressive oligodeoxynucleotides or a combination of two or more thereof aforementioned above with a length between 22-30 nucleotides as stated in dependent claim 79 possess the abilities of reducing the production of a cytokine or chemokine in the subject and reducing the production of a cytokine or chemokine in a cell *in vitro*. Therefore the specification does not provide adequate description of the claimed genus suppressive oligodeoxynucleotides (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21), or a combination (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) of two or more thereof.

The specification, does not disclose distinguishing and identifying features of a representative number of members of the genus of suppressive oligodeoxynucleotides aforementioned above, or a combination of two or more thereof, to which the claims are drawn, such as a correlation between the structure of the suppressive oligodeoxynucleotides or a combination of two or more thereof aforementioned above and its recited function reducing the production of a cytokine or chemokine in the subject and reducing the production of a cytokine or chemokine in a cell *in vitro* so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of suppressive oligodeoxynucleotides or a combination of two or more thereof aforementioned above.

Moreover, Examples 1, 2, and 3 specifically teach a method of reducing the production of CpG induced cytokine or chemokine aforementioned above and reducing the production of CpG induced cytokine or chemokine aforementioned above in a cell *in vitro*, comprising administering a therapeutically effective amount of a suppressive oligodeoxynucleotide to a subject, wherein the suppressive oligodeoxynucleotide is SEQ ID NO: 1 which consist of a length of 16 nucleotides. However the rejected claims are directed to a method of reducing the production of a cytokine or chemokine in the subject and reducing the production of a cytokine or chemokine in a cell *in vitro*, comprising administering a therapeutically effective amount of a suppressive oligodeoxynucleotide to a subject, wherein the suppressive oligodeoxynucleotide comprises from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) and do not meet the written description requirements.

MPEP § 2163.02 states, “[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ”. The courts have decided: The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, “[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention” (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed. The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus aforementioned above, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of suppressive oligodeoxynucleotides aforementioned above, or a combination of two or more thereof with the recited activities. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of suppressive oligodeoxynucleotides aforementioned above is not deemed representative of the genus of suppressive oligodeoxynucleotides (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) thereof to which the claims refer and therefore the claimed invention is not properly disclosed even though SEQ ID NO:1 meet the written description provision of 35 USC 112, first paragraph.

Enablement

4. Claims 35, 46-47, 54, 60-87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing the production of TNFα, MIP-2, IL-6, and KC induced by CpGs in a subject comprising administering to the subject the suppressive oligodeoxynucleotide SEQ ID NO: 1; also while being enabling for a method of reducing the production TNFα, MIP-2, IL-6, and KC induced by CpG in a cell *in vitro*, comprising contacting the cell with the suppressive oligodeoxynucleotide SEQ ID NO: 1, does not reasonably provide enablement for a method of reducing the production of a cytokine or chemokine in a subject, comprising administering solely to the subject a suppressive oligodeoxynucleotide, wherein the oligodeoxynucleotide comprises from 2 to 4 guanosine-rich

sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1 SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof (clam 1), comprising administering solely to the subject a therapeutically effective amount of an oligodeoxynucleotide comprising the nucleic acid sequence set forth as SEQ ID NO: 1 (claim 46), a method of reducing the production of a cytokine or chemokine in a cell *in vitro*, comprising contacting the cell solely with a suppressive oligodeoxynucleotide, wherein the suppressive oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof (claim 54). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B)The nature of the invention;
(C)The state of the prior art;
(D)The level of one of ordinary skill;
(E)The level of predictability in the art;
(F)The amount of direction provided by the inventor;
(G)The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The claims are drawn to a method of reducing the production of a cytokine or chemokine in a subject, comprising administering to the subject a suppressive oligodeoxynucleotide, wherein the oligodeoxynucleotide comprises from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof, thereby reducing the production of the cytokine or chemokine in the subject (claim 35); a method of reducing the production of a cytokine or chemokine in a subject, comprising administering to the subject a therapeutically effective amount of an oligodeoxynucleotide comprising the nucleic acid sequence set forth as SEQ ID NO: 1, thereby reducing the production of the cytokine or chemokine in the subject (claim 46), a method of reducing the production of a cytokine or chemokine in a cell *in vitro*, comprising contacting the cell with a suppressive oligodeoxynucleotide, wherein the suppressive oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof (claim 54).

Breadth of the claims: The claims encompass the suppressive oligodeoxynucleotides (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) that reduce the production of any given cytokine or chemokine in the subject in a method of reducing the production of any given cytokine or chemokine in a cell *in vitro.*

Guidance of the specification/The existence of working examples:

The specification discloses a suppressive ODN H154 (SEQ ID NO: 1), CpG ODN 1555 (SEQ ID NO: 27), and a neutral ODN 1612 in Examples (see Example 1 (see pp. 32-33). The specification discloses CpG DNA stimulates RAW 264.7 cells to produce a variety of cytokines and chemokines (TNFα, MIP-2, IL-6, and KC) (see Example 2 (see pp. 34-35)). The specification discloses the suppressive ODN to CpG-stimulated RAW 246.7 cells significantly reducing production of the pro-inflammatory molecules (see Figure 2 and pg. 35 Example 2). The specification discloses when suppressive ODN were co-administered with the CpG DNA, the suppressive ODN blocks the CpG DNA-induced inflammation of the mouse lung by reducing the production (TNFα, MIP-2, IL-6, and KC), wherein, the CpG DNA triggered the production of pro-inflammatory cytokines and chemokines (TNFα and MIP-2) (see Example 3 (see pp. 35-36 and Figs. 3 and 4).

Moreover, the specification defines immunostimulatory CpG motifs as imunostimulatory sequences that trigger macrophages, monocytes and lymphocytes to produce a variety of pro-inflammatory cytokines and chemokines (see pg. 12 lines 10-15). The specification also states that suppressive oligodeoxynucleotides and guaunosine-quadruplexes (G-tetrads) relates to the use of a class of DNA motifs that selectively inhibits or suppresses immune activation and are useful for inhibiting an immune response and for blocking immunostimulation caused by CpG motifs in vivo and in vitro (see pg. 19 lines 26-30 and pg. 20 lines 1-5). The specification discloses any oligodeoxynucleotides capable of forming G-tetrads may be used to suppress CpG DNA-induced immune activation (see pg. 21 lines 10-20).

Therefore the specification is limited to a method of reducing the production of TNFα, MIP-2, IL-6, and KC induced by CpG ODN in a subject comprising administering a suppressive oligodeoxynucleotide set forth as SEQ ID NO: 1. However, said data indicated does not provide a correlation between the structure of the claimed oligodeoxynucleotide and the functions set forth in the instant claims. Moreover, the limited number of suppressive oligodeoxynucleotide (i.e. SEQ ID NO: 1) aforementioned above disclosed is not deemed to be representative of the genus encompassed by the instant claims.

Applicants have not demonstrated that all cytokines and chemokines are reduced when administering to a subject, the genus of suppressive ODNs or a combination of two or more thereof aforementioned above. Although the specification defines immunostimulatory CpG motifs and discloses that suppressive oligodeoxynucleotides capable of forming G-tetrads may be used to suppress CpG DNA-induced immune activation, the specification does not provide guidance as to how to distinguish which ODNs are specifically suppressive or immunostimualtory CpG stimulated which indicate producing or reducing cytokines or chemokines as claimed in the recited method. Applicants have not demonstrated that any examples aforementioned above are representative of the genus of oligonucleotides excluding SEQ ID NO: 1 or a combination including SEQ ID NO: 1 for the recited methods as claimed. Moreover, Applicant has not demonstrated that suppressive oligodeoxynucleotides or a combination of two or more thereof aforementioned above with a length between 22-30 nucleotides as stated in dependent claim 79 possess the abilities of reducing the production of a cytokine or chemokine in the subject and reducing the production of a cytokine or chemokine in a cell *in vitro*.

The specification discloses SEQ ID NO: 1 as a suppressive oligodeoxynucloetide (ODN), which meets the enablement requirement. However the rejected claims are directed to a method of reducing the production of a cytokine or chemokine in the subject and reducing the production of a cytokine or chemokine in a cell *in vitro*, comprising administering a therapeutically effective amount of a suppressive oligodeoxynucleotide to a subject, wherein the suppressive oligodeoxynucleotide comprises from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) and do not meet the enablement description requirements.

Therefore the data fails to show a method of reducing the production of any given cytokine or any given chemokine with the suppressive oligodeoxynucleotide comprising from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21). Therefore, one skilled in the art would not accept on its face the examples given in the specification as being correlative or representative of a successful model. The specification is devoid of any teaching that the claimed suppressive oligodeoxynucleotides (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) in the recited method.

In conclusion, the claimed invention is not enabled for the recited method of reducing the production of a cytokine or chemokine comprising administering solely to the subject a suppressive oligodeoxynucleotide, wherein the oligodeoxynucleotide comprises from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1 SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof (clam 1), comprising administering solely to the subject a therapeutically effective amount of an oligodeoxynucleotide comprising the nucleic acid sequence set forth as SEQ ID NO: 1 (claim 46); the claimed invention is not enabled for the recited method of reducing the production of a cytokine or chemokine in a cell *in vitro*, comprising contacting the cell solely with a suppressive oligodeoxynucleotide, wherein the suppressive oligodeoxynucleotide comprises the nucleic acid sequence set forth as one of SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21, or a combination of two or more thereof (claim 54). The claims encompass the suppressive oligodeoxynucleotides (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) that reduce the production of any given cytokine or chemokine in the subject in a method of reducing the production of any given cytokine or chemokine in a cell *in vitro*. Therefore the specification is limited to a method of reducing the production of TNFα, MIP-2, IL-6, and KC induced by CpG ODN in a subject comprising administering a suppressive oligodeoxynucleotide set forth as SEQ ID NO: 1. Therefore the data fails to show a method of reducing the production of any given cytokine or any given chemokine with the suppressive oligodeoxynucleotide comprising from 2 to 4 guanosine-rich sequences, wherein the oligodeoxynucleotide comprises the nucleic acid sequence (SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21) or a combination of two or more suppressive oligodeoxynucleotides thereof (SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 21). Therefore, one skilled in the art would not accept on its face the examples given in the specification as being correlative or representative of a successful model. In view of the lack of support in the specification for the claimed invention, the claims are not enabled. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed invention.

Conclusion

5. No claims allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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